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## Drug safety in the balance: past, present and future

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All effective medicines have unwanted effects, usually adverse effects. Prior to the introduction of the modern licensing process in the 1960s there was little or no formal assessment of efficacy or safety. Since then, new medicines have had to demonstrate safety, quality and efficacy to the satisfaction of a regulatory body. Initial assessments of safety and efficacy have usually been based on randomized trials (RCTs), but as safety is always provisional, the need for study of effects not seen in RCTs is obvious.

Most of the time, further assessment does not change the risk/benefit balance markedly, and most actions are taken simply to inform prescribers and patients of actual or possible hazards of particular medicines. In some cases, sub-groups are identified in whom the balance is adverse and contra-indications are given or a drug may become second-line.

Examples of situations in the past decade where actions have been taken in regard to safety will be described. These include selegiline (an anti-Parkinsonian drug) and mortality, hormone replacement therapy and cancer and cardio-vascular disease, cerivastatin and rhabdomyolysis and Cox-2 inhibitors with coronary heart disease.

The current processes for detecting and evaluating “signals” of new problems will be described. There have been advances in the processing of spontaneous reports of suspected adverse drug reactions and these help both to prioritize signals so that those that are more likely to be truly causal are investigated first, but also to show where signals come from “innocent bystander” drugs.

Important changes in the regulatory environment are taking place; notably, “risk management” initiatives. Some of these changes have the potential to make a real

difference, but so far they have not been assessed carefully and have not been demonstrated to be effective in public health terms.

There is a need for improvements to the whole process and some suggestions for better use of existing data and new methods to obtain data will be given.



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